



# UNITED STATES PATENT AND TRADEMARK OFFICE

MN  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,585	05/02/2001	Victor Gogolak	QED0001	6776
25227	7590	07/13/2007	EXAMINER	
MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 400 MCLEAN, VA 22102			BUSS, BENJAMIN J	
		ART UNIT	PAPER NUMBER	
		2129		
		MAIL DATE	DELIVERY MODE	
		07/13/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/681,585	GOGOLAK, VICTOR
	Examiner	Art Unit 2129
	Benjamin Buss	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 January 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-5,7-12 and 14-28 is/are rejected.  
 7) Claim(s) 6,13 and 27 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 13 July 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 9/10/2002.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

This Office Action is in response to an AMENDMENT filed 7/13/2006 (entered 3/28/2007) for the patent application 09/681,585 filed on 5/2/2001. Claims 1-28 are pending.

5

**Drawings*****Response to Arguments***

Applicant's arguments, see page 15, filed 7/13/2006, with respect to the drawing objections have been fully considered and are persuasive. The objections to the drawings have been withdrawn.

10

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15      Claims 4, 11, 18, 20-21, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 4, 11, 18, and 25: The intended meaning of the phrase "characteristics in drug/reaction/demographic information" is not clear. The phrase has been interpreted to mean "involving at least one of: drug information, reaction information and demographic information."

20      -      Claims 20-21 are rejected by virtue of their dependence on a rejected base claim.

Appropriate corrections are required.

***Response to Arguments***

Applicant's arguments, see page 15, filed 7/13/2006, with respect to the rejections under 35 U.S.C. §112, second paragraph, have been fully considered and are persuasive. The previous rejection of claims 1-28 under 35

25      U.S.C., second paragraph, has been withdrawn. A new rejection of claims 4, 11, 18, 20-21, and 25 has been presented above.

SpecificationResponse to Arguments

Applicant's arguments, see page 15, filed 7/13/2006, with respect to the specification objections have been fully considered and are persuasive. The objections to the specification have been withdrawn.

5

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-8, 11, 14-15, 18, 21-22, 25, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by **Szarfman** ("New Methods for Signal Detection").

15

**Claims 1, 8, 15, and 22:**

**Szarfman** anticipates:

- a selector for identifying at least one drug of interest (p1-56 especially "Detection of 'higher than expected' signal scores" p23 or "data extraction" p32 or "scores ... associated with a specific drug" p48);
- a profiler for selecting from multiple profiles related to safety of the at least one drug of interest, using at least one filter to determine at least one set of cases (p1-56 especially "Drug-event combinations by drug, drug class, event, event group, and time interval" p23 or "stratification" p28 or "age specific exposure" p30 or "derived from application of a statistical model to identify the ones observed at higher than expected frequencies" p32);
- at least one data mining engine for processing the at least one set of cases determined and submitted by the at least one filter (p1-56 especially "Data Mining" p23 or "identifying and documenting many serious rare adverse drug reactions" p26 or "gender-based patterns" p29 or "estimate SS" p32 or "model DERIVED from the data" p42); and
- an output device for displaying analytic results from the data mining engine (p1-56 especially "each distinct combination of any drug, event, sex, time, and age group" p35 or "predict patients at risk" p56).

Art Unit: 2129

**Claims 2, 9, 16, and 23:**

**Szarfman** anticipates:

- wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set  
5 of the reactions to the drug of interest (p1-56 especially p43 or p48).

**Claims 3, 10, 17, and 24:**

**Szarfman** anticipates:

- wherein the data mining engine is a comparator to measure reactions to the drug of interest against a  
10 user-defined backdrop (p1-56 especially p51 or p53).

**Claims 4, 11, 18, and 25:**

**Szarfman** anticipates:

- wherein the data mining engine is a correlator to look for correlated signal characteristics in  
15 drug/reaction/demographic information (p1-56 especially p23 or p32 or p35 or p42 or p49).

**Claims 5, 12, 19, and 26:**

**Szarfman** anticipates:

- wherein the data mining engine is at least two members of the group consisting of: a proportional analysis  
20 engine (p1-56 especially p43 or p48), a comparator (p1-56 especially p51 or p53), and a correlator (p1-56 especially p23 or p32 or p35 or p42 or p49).

**Claims 7, 14, 21, and 28:**

**Szarfman** anticipates:

- wherein the system permits assessment and analysis of risks of adverse effects resulting from use of at  
25 least one drug of interest in any of multiple dimensions of risk assessment and analysis (p1-56 especially p32 or p42 or p49).

Art Unit: 2129

**Allowable Subject Matter**

Claims 6, 13, and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Arouh (USPGP 2004/0030503)
- Bergman (USPGP 2004/0015372)
- Karel ("Tasks of Food Technology in the 21<sup>st</sup> Century")
- 10 - Guo ("Comparison and Analysis of the National Drug Code Systems Among Drug Information Databases")
- Stead ("Integration and Beyond: Linking Information from Disparate Sources and into Workflow")

Claims 1-28 are rejected.

15

**Correspondence Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Buss whose telephone number is 571-272-5831. The examiner can normally be reached on M-F 9AM-5PM.

As detailed in MPEP 502.03, communications via Internet e-mail are at the discretion of the applicant.

20 Without a written authorization by applicant in place, the USPTO will not respond via Internet e-mail to any Internet correspondence which contains information subject to the confidentiality requirement as set forth in 35 U.S.C. 122. A paper copy of such correspondence will be placed in the appropriate patent application. The following is a sample authorization form which may be used by applicant:

"Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

25

Art Unit: 2129

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Vincent can be reached on 571-272-3080. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application

- 5 Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Benjamin Buss  
Examiner  
Art Unit 2129

/BB/

10

DAVID VINCENT 7/4/07  
SUPERVISORY PATENT EXAMINER